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Direct Investigation Report
Social Welfare Department's Monitoring of
Services of Residential Care Homes for the Elderly

The Office of the Ombudsman is concerned about reports appearing in the media from time to time alleging that some residential care homes for the elderly ("RCHEs") treated residents with neglect and even abused the residents. The society at large demands that the Government should strengthen its monitoring of RCHEs and improve the current regulatory legislation to prevent recurrence of the above problems. In this light, The Ombudsman has conducted this direct investigation.

Our direct investigation reveals inadequacies in four areas with regard to the monitoring of RCHE services by the Social Welfare Department ("SWD").

(1) Relevant laws are antiquated with no amendments made in more than 22 years. Hence, the laws are incomprehensive and with limited effects;

(2) Enforcement is lax;

(3) Inspection mechanism is inadequate; and

(4) Provision of information on non-compliance by RCHEs is incomprehensive.

The Ombudsman has made seven improvement recommendations to SWD and expects the Department to strengthen all aspects of its monitoring of services provided by RCHEs.

The executive summary of the direct investigation report is at **Annex 1**.

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Direct Investigation Report
Government's Regulation of Proprietary Chinese Medicine

The Office of The Ombudsman has completed a direct investigation into the Government's regulation of proprietary Chinese medicine ("pCm").

The provisions in the Chinese Medicine Ordinance ("CMO") covering registration for pCm took effect in 2003. However, our investigation has found that of those over 18,000 applications for registration of pCm, only less than 10% succeeded in obtaining full registration as at 30 June 2018, i.e. 15 years after the enactment of the legislation. More than one-third of the applications are still holding transitional registration. Nevertheless, those pCm with transitional registration are still available in the market, and some of them have been selling for nearly 20 years. The situation is very undesirable.

The Office has also found that many health food products with Chinese medicines as the main ingredients have appeared in the market. As long as other non-Chinese medicine ingredients are added, such products can be sold in the market without registration. While some of them bear the same names as registered pCm, they are not subject to the regulation under the CMO. Some even contain Chinese medicines with strong toxicity listed in Schedule 1 of the CMO, which may endanger people's health.

On the other hand, people in the trade have indicated that the current registration system for pCm is harsh and complicated. Besides, the Government's technical support is inadequate. Moreover, there is currently no registration or certification system for Chinese medicine pharmacists in Hong Kong, which is not conducive to the long-term development of the industry.

We strongly urge the Food and Health Bureau and the Department of Health, the department that assists the Chinese Medicine Council of Hong Kong to take the following recommendations:

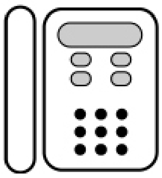
(1) to review thoroughly the current registration system for pCm and the CMO;

(2) to amend the relevant provisions of the Ordinance;

(3) to prevent the proliferation of undesirable drugs and health food products in the market, in order to safeguard public health;

(4) to take measures to assist the trade, and strengthen their communication with the trade to promote its healthy development.

The Ombudsman has made 12 improvement recommendations to the Government. The executive summary of the investigation report is at **Annex 2**.



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Office of The Ombudsman
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Annex 1

Executive Summary

Direct Investigation into Social Welfare Department's Monitoring of Services of Residential Care Homes for the Elderly

Foreword

With the continuously ageing population in Hong Kong, the demand for services of residential care homes for the elderly ("RCHEs") has become more intense, and the service standard of RCHEs has attracted much public attention. The Social Welfare Department ("SWD"), being the authority responsible for monitoring RCHEs, has the duty to oversee the operations of all local RCHEs (including subvented RCHEs and private RCHEs[1]) to ensure that they provide up-to-standard service and care to their residents. However, there have been media reports from time to time alleging that some RCHEs treated residents with neglect or even uncovering incidences of elder abuse[2] in RCHEs. The society at large demands that the Government strengthen its monitoring of RCHEs and improve the existing legislation to prevent recurrence of the above problems. In this light, The Ombudsman initiated this direct investigation to probe any inadequacies regarding SWD's monitoring of RCHEs, with a view to making recommendations for improvement.

Our Findings

2. SWD monitors the operations of all RCHEs through a licensing scheme under the Residential Care Homes (Elderly Persons) Ordinance ("the Ordinance") and the Residential Care Homes (Elderly Persons) Regulation ("the Regulation"). In addition, the Code of Practice for Residential Care Homes (Elderly Persons) ("the Code"), issued by the Director of Social Welfare ("the Director") pursuant to the Ordinance, sets out the principles, procedures, guidelines and standards for operators' compliance with regard to how they should operate, keep, manage or in any other way manage RCHEs.

3. The Licensing Office of Residential Care Homes for the Elderly

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[1] Subvented RCHEs are operated by non-Governmental organisations and subsidised by the Government. Private RCHEs are operated and funded by individuals or private organisations.

[2] SWD's Procedural Guidelines for Handling Elder Abuse Cases defines elder abuse as: "Generally speaking, elder abuse refers to the commission or omission of any act that endangers the welfare or safety of an elder."

(“LORCHE”) under SWD is responsible for processing all applications for and renewal of RCHE licences. The Ordinance provides that if an RCHE licence holder commits an offence under the Ordinance, LORCHE may cancel, suspend or refuse to renew the licence, or amend any condition of the licence. For the purpose of monitoring RCHEs, LORCHE has set up four professional inspectorate teams to conduct inspections at RCHEs with respect to the four aspects specified in the RCHE licence, namely, social work, health care and hygiene, building safety and fire safety. If irregularities are found during inspections, LORCHE would, depending on the gravity of the irregularities, take enforcement actions against the RCHE in question. The actions may include issuing an advice, a warning or “direction on remedial measures”[3] (“DRM”) pursuant to the Ordinance. Follow-up inspections would also be conducted to check if the RCHE in question has made improvements.

4. This Office finds the following inadequacies with regard to SWD’s monitoring of services provided by RCHEs.

(I) Current Laws Antiquated, Incomprehensive and with Limited Effects

5. Since the enactment on 1 June 1996 of the Ordinance and the Regulation, for over 22 years, no amendments have ever been made to the important requirements specified therein regarding staffing level and other operational matters of RCHEs. This Office notices that over the years there have been demands in society for amendments to the Ordinance and the Regulation. While SWD is already conducting a review on the legislative amendments and anticipates completion of the review and initiation of the legislative procedures in mid-2019, it is possible that the legislative amendments may still take years to complete. Meanwhile, the various serious breaches by some RCHEs (such as infringement of the residents’ privacy, wrong administration of drugs, improper use of restraints, etc.), which may result in physical and mental harm in residents, are not indictable offences under the Ordinance and the Regulation. Besides, the scope of monitoring under the current legal framework does not cover such regular services as escorting residents and accompanying them to attend medical consultations outside the RCHE premises. We consider that SWD should also review this issue with a view to ensuring that residents are properly taken care of by RCHE staff when they go out for medical consultations.

[3] Section 19 of the Ordinance provides that the Director may, in respect of any residential care home, by notice in writing, give directions on remedial measures as appear to him to be required to secure that it is operated and managed satisfactorily. The Director shall indicate a period within which the directions shall be complied with.

(II) Lax Enforcement

6. SWD's enforcement against under-performing RCHEs or those RCHEs committing the offences under the Ordinance has been lax. The enforcement measures it implemented not only lacked deterrent effects, but also failed to induce timely and effective improvements by those RCHEs with irregularities. The Department must promptly address the following inadequacies in its enforcement actions.

(1) **Cancellation of Licence:** During the four years between 2014/15 and 2017/18, SWD had not cancelled any RCHE licence. Nevertheless, there was a case where the RCHE concerned had repeatedly committed serious breaches. SWD should have considered cancelling its licence. Although strict enforcement of cancellation of RCHE licences may cause some RCHEs to close down, making it even more difficult for the elderly to find accommodation, the ultimate victims will still be the elderly if RCHEs repeatedly commit serious breaches. Rigorous enforcement actions can generate deterrent effects to RCHEs, alerting them to ensure their service quality, which, in turn, benefits the elderly.

(2) **Institution of prosecution:** Where the breaches committed by an RCHE are of a serious nature or magnitude, LORCHE will issue a warning or, pursuant to the Ordinance, a DRM to the RCHE. During the three years between 2014/15 and 2016/17, SWD had issued some 300 to 400 warnings and DRMs to RCHEs each year. The conviction rate was, however, rather low, with only 16 cases in three years. In 2017/18, the offenders in 23 prosecutions were convicted, representing an increase in the number of conviction cases. We expect SWD to continue to strengthen its rigorous enforcement actions.

(3) **Setting deadline for improvement measures and timetable for follow-up inspections after issuing warnings:** When SWD issues a DRM, it normally requires the RCHE committing breaches to rectify the problem within 14 to 30 days. Upon expiry of the deadline, SWD will conduct follow-up inspections. Nevertheless, SWD has not set any deadline for implementing improvement measures, nor a timetable for conducting follow-up inspections after issuing a warning. Where an RCHE is issued a warning for a serious breach, the breach

represents violation of the Ordinance/Regulation (such as failing to meet staffing requirement). The gravity of the breach is no less than that of acts which would justify the issuance of a DRM (such as improper use of restraints). In our view, SWD should set a deadline for implementing improvement measures and a timetable for conducting follow-up inspections after issuing a warning against any irregularities.

(4) **Delay in taking or taking no enforcement action:** Another case revealed that SWD had failed to follow established procedures to issue a warning within 7 working days to an RCHE for failure to meet statutory staffing requirement. Instead, SWD issued a warning to the RCHE in question some five months later, and it had not conducted any timely follow-up inspection to check whether the problem was rectified. Furthermore, SWD had not conducted an in-depth investigation into the suspected falsified staff duty roster submitted by the RCHE in question, while provision of false information is an indictable offence that SWD can prosecute under the Ordinance.

(5) **Following-up elder abuse cases:** Currently, elder abuse is not an offence under the Ordinance/Regulation and hence SWD is not empowered to institute prosecution directly in this regard. However, SWD can issue a DRM to the RCHE in question, requiring the latter to improve or rectify the situation. Should SWD find that the RCHE has not complied with the DRM, SWD can institute prosecution pursuant to the Ordinance. Moreover, under the Ordinance, the Director may cancel, suspend or refuse to renew the licence of an RCHE, or amend any condition of the licence on the ground that the licence holder has been convicted of an offence under the Ordinance or any indictable offence. In one suspected elder abuse case where an RCHE resident died, there was no record showing that SWD had actively enquired of the Police and the coroner’s court of their findings so as to decide what enforcement action should be taken against the RCHE in question.

(III) Inspection Mechanism

7. The current inspection mechanism of SWD has the following inadequacies:

(1) **Effectiveness of comprehensive inspections questionable:** LORCHE conducts regular comprehensive inspections of RCHEs to examine all the specified items under regulation in the aspects of social work and health care and hygiene. Apart from examining the environmental safety and hygiene, facilities and manpower of an RCHE, LORCHE inspectors also have to check the employment records of staff, and personal records of residents of the RCHE. Moreover, the inspectors have to interview residents and their family members, and observe whether the RCHE has made due arrangements for administration of drugs, meals and baths for residents. As each item of the inspections has to be checked and observed carefully, and details of inspection have to be recorded against a checklist, the workload is quite heavy. Nevertheless, such duty is usually carried out by one or two inspectors and completed within half a day or one day. It is questionable whether the inspectors can conduct a comprehensive, in-depth, and effective inspection of an RCHE's operation within such a short period of time. The saving grace is that, in recent years, additional resources have been earmarked and retired officers from disciplined forces have been recruited to strengthen SWD's inspection work. We expect that SWD will continue with their efforts to further enhance the effectiveness of their inspections.

(2) **Inspections of subvented RCHEs**: For private RCHEs, LORCHE conducts at least three inspections each year in the aspects of social work and health care and hygiene. However, for subvented RCHEs, the frequency of inspection used to be only at least once every three years in those aspects, which was obviously less than that with private RCHEs. After we commenced our direct investigation, LORCHE has since April 2017 increased its inspections of subvented RCHEs to at least once annually, but it is still less frequent than the inspections of private RCHEs. LORCHE should consider further increasing the frequency of inspections of subvented RCHEs.

(IV) Provision of Information on Non-compliance by RCHEs

8. In the past, SWD only posted on its website the conviction records of RCHEs in breach of the Ordinance/Regulation, but did not publish any other irregularities identified by it. Since 1 April 2018, SWD has started to upload on its website the records of warnings and DRMs issued to RCHEs with irregularities for public viewing.

9. Nevertheless, apart from issuing warnings and DRMs, SWD can also take licence enforcement actions against RCHEs with irregularities, including suspension of RCHE licence, refusal to renew the licence, or decision to amend any licensing conditions. SWD should also disclose such information to the public.

Recommendations

10. In the light of the above, The Ombudsman makes the following recommendations to SWD:

Reviewing and Amending the Ordinance

(1) It brooks no delay to review and amend the relevant legislation. SWD, jointly with the policy bureaux concerned, should initiate amendments to the Ordinance as soon as possible, including considering extension of the legislative scope to cover offences currently not within the purview of the Ordinance and the Regulation (such as infringement of the privacy of residents, wrong administration of drugs, improper application of restraints, and elder abuse, etc.). SWD should also explore the viability of bringing under its supervision the services of escorting residents and accompanying them to attend medical consultations provided by RCHE staff.

Strengthening Enforcement Actions

(2) SWD should strengthen its enforcement actions, including taking enforcement actions in a timely and rigorous manner against RCHEs with irregularities. It should also step up prosecution and/or licence enforcement actions, such as cancellation of licence, against those

RCHEs which have repeatedly and seriously violated the relevant legislation/licensing requirements.

(3) All suspected elder abuse cases should be followed up diligently. For serious incidents (such as death of residents), SWD should actively and regularly follow up such cases with the Police and/or the court, so as to take timely and corresponding action against the RCHEs in question once the Police or the court has reached a conclusion. For instance, regarding confirmed cases of elder abuse, SWD should issue a DRM in a resolute manner. If the RCHEs in question fail to comply, SWD should institute prosecution pursuant to the Ordinance.

Stepping up Inspections

(4) The operation and effectiveness of comprehensive inspections should be reviewed. Where necessary, SWD should augment and/or deploy manpower resources to conduct comprehensive inspections to ensure that its inspections of RCHEs are truly comprehensive, in-depth, and effective.

(5) SWD should continue to strengthen its follow-up inspections after issuing warnings and DRMs, and set a deadline for RCHEs with warnings issued to rectify the relevant irregularities and a timetable for LORCHE to conduct follow-up inspections at those RCHEs.

(6) The inspections of subvented RCHEs should be further strengthened.

Enhancing Information Transparency

(7) Apart from publishing its records of warnings and DRMs issued and convictions of RCHEs, SWD should also post on its website information about other enforcement actions (such as suspension of RCHE licence, refusal to renew the licence, or decision to amend any licensing conditions), both for public reference and to urge the RCHEs concerned to improve their services.

Office of The Ombudsman
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Annex 2

Executive Summary
Direct Investigation Report

Government's Regulation of Proprietary Chinese Medicine

Foreword

Since the provisions in the Chinese Medicine Ordinance ("CMO") (Cap. 549) covering registration of proprietary Chinese medicine ("pCm") took effect in 2003, only a small portion of applications for registration of pCm have been issued the Certificate of Registration ("HKC"). Meanwhile, many purported "health food products" have appeared in the market, their main ingredients being Chinese herbal medicines. However, as long as other non-Chinese medicine ingredients such as wheat and minerals are added to these products, they can be on sale in the market without registration under the CMO. People are thus concerned about the quality and safety of such "Chinese medicine health food products" ("CM health products").

Our Findings

2. Our investigation has revealed inadequacies on the part of the Food and Health Bureau ("FHB") and Department of Health ("DH") in the following four areas.

(1) Definition under CMO Leaves Loopholes in Regulation

3. At the vetting stage of the CMO, the words "composed solely of" were added to the definition of pCm, which has caused loopholes in regulation. We have compared a number of registered pCm in the market with "CM health products" bearing similar names and containing Chinese medicines but are not required to be registered. We found that with identical names, similar ingredients and purported effects, and even the same manufacturer as pCm, those "CM health products" can circumvent the regulation under the CMO as long as ingredients other than Chinese medicines (e.g. grape seed) are added in the products, regardless of their composition and drug effect. Moreover, some of those products contain Chinese herbal medicines with strong toxicity listed in Schedule 1 of the CMO, which may be hazardous to people's health.

4. FHB and DH have indicated that they will regulate those "CM health products" in accordance with other relevant legislation and regulation, such as the Public Health and Municipal Services Ordinance, and the Food and Drugs (Composition and Labelling) Regulations. Nevertheless, the above laws do not focus on the safety, quality and efficacy of the products, and they have their limitations. For example, when the Centre for Food Safety under the Food and Environmental Hygiene Department conducts random checks on pCm, it aims to assess the risk of their consumption. Therefore, it will not test whether those "CM health products" actually contain the claimed Chinese herbal medicines, let alone to test their efficacy. Moreover, prosecutions against unregistered pCm for violation of those legislation are few and far between.

5. The Government agrees that there should be more stringent regulation of those purported "CM health products". In this light, the Medicines Board under the Chinese Medicine Council of Hong Kong ("CMCHK") has set up a taskforce to conduct a comprehensive review and give comments regarding amendment to the definition of pCm (including its scope).

(2) Slow Progress of Registration

6. There are three types of certificate/notice in the registration of pCm, namely: (1) HKC; (2) the Notice of confirmation of transitional registration of proprietary Chinese medicine" ("HKP"); and (3) the Notice of confirmation of (non-transitional) registration application of proprietary Chinese medicine ("HKNT"). HKP and HKNT are intended to be transitional arrangements for the registration system. Since the provisions requiring mandatory registration of pCm under the CMO were implemented in 2010, these transitional arrangements have been in place for eight years already, and the "final deadline" for submission of relevant documents (30 June 2015) set by the Medicines Board expired three years ago. As at 30 June 2018, there were over 18,000 applications for registration of pCm, but only less than 10% (1,539 cases) succeeded in obtaining HKC. The number was even less than applications rejected/withdrawn. Of all the applications, more than one-third are still holding transitional registration (including 6,781 HKP cases and 58 HKNT cases). For HKP, only those pCm manufactured, sold or supplied for sale in Hong Kong on or before 1 March 1999 can apply. In other words, most of the transitional products (HKP) have been on sale for nearly 20 years and yet they still could not get HKC.

7. Members of the public may not be able to tell the difference between HKP, HKNT and HKC. Besides, since it is very difficult to obtain HKC, and those HKP/HKNT holders are still allowed to be sold in the market, there is less incentive for the manufacturers to invest and seek full registration after obtaining HKP.

8. In our view, that so many applicants are still holding HKP and HKNT after a long period indicates that the Government has not set any clear objective and time schedule for transforming the HKP and HKNT cases into HKC. Moreover, if the Government does not see any problem with those HKP and HKNT products being sold in the market for such a long time, people may doubt whether the requirement for HKC is necessary and justifiable.

(3) Inadequate Support and Lack of Communication with the Trade

9. People in the Chinese medicine trade have expressed a lot of opinions regarding the current regulatory system and registration requirements, notably the shortage of qualified laboratories, the harsh registration requirements, and the high costs involved. Although DH has adopted a number of measures to support the trade, the traders generally consider the technical support from the Government still inadequate. The Government's failure to address this issue may hinder the long-term development of pCm.

10. The Government has on one hand imposed stringent regulatory requirements on the registered pCm, but on the other hand failed to plug the existing legal loopholes regarding "CM health products" which are not subject to control of the CMO. This is tantamount to encouraging the manufacturers to continue selling their pCm under the cover of health food products. It will inevitably undermine the public's confidence in the current regulatory system.

(4) Consider Setting up a Certification System for Chinese Medicine Pharmacists

11. Several universities in Hong Kong offer degree programmes in Chinese medicine. However, Chinese medicine pharmacist has not been recognised as a professional qualification. Unlike pharmacists in western medicine, there is currently no registration or certification system for Chinese medicine pharmacists in Hong Kong. On the other hand, our neighbour Macao will soon set up a new registration system for Chinese medicine pharmacists to establish their legal status and professional

recognition. Its development is ahead of Hong Kong.

12. To expedite the processing of applications for pCm registration, DH has beefed up its manpower. However, the newly recruited Assistant Chinese Medicine Officers are employed on limited term contracts. This means that the extra staff are merely for meeting transient operational needs. Given that more than 6,000 applications for HKP are still under processing, it is essential for the Government to review the manpower arrangements.

Conclusion

13. **The CMO was enacted with the intent of preventing unregistered pCm from spreading in the market and thus endangering people's health. Regrettably, since the enactment of the CMO in July 1999, nearly two decades have passed and yet over 80% of the registered pCm have not been issued HKC. FHB and DH should be held accountable for the slow progress. What is more worrying is that some manufacturers have taken advantage of the legal loopholes by adulterating certain pCm, which are required to be registered, with non-Chinese medicine ingredients. As a result, the pCm was "transformed" into health food products, thereby circumventing regulation under the CMO. Such shortcut of "less investment, less regulation" must be blocked as soon as possible. Otherwise, the proliferation of "CM health products" in the market may become a threat to public's health.**

Recommendations

14. In the light of the above, The Ombudsman makes 12 improvement recommendations to the Government.

Review of Current Legislation

15. **FHB** should quickly review whether any amendments to the relevant provisions of the CMO are necessary, covering the following areas:

(1) to plug the legal loopholes in the definition of pCm as soon as possible;

(2) to impose more stringent regulation on those health food products containing Chinese medicines with stronger toxicity listed in Schedule 1 of the CMO, making it mandatory for these products to obtain

registration;

(3) to restrict “CM health products” from using the same names as pCm;

(4) to require all products containing Chinese medicine to adopt the Chinese and English names given in the Schedules of the CMO when listing out their ingredients; and

(5) to regulate the efficacy claims of “CM health products”.

Addressing the Registration System

(6) **DH** should help the CMCHK in reviewing the current registration system, explore why a large number of applicants are still holding transitional registration after such a long period, and implement effective measures focusing on assisting those applicants to obtain full registration as soon as possible.

(7) **DH** should help the CMCHK to set a target timeframe for transforming the more than 6,000 transitional registrations into full registration, and review any need for more staff to handle the vetting and approval work.

(8) **DH** should consider engaging more specialists in Chinese medicines to assist the CMCHK in devising the registration system and vetting applications.

Strengthening Communication with the Trade and Offering More Support

(9) **DH** should strengthen its communication with the trade and various stakeholders (including academics and laboratories).

(10) **DH** should provide more assistance to the trade in resolving the problems in pCm registration, such as expanding the number of accredited Mainland drug testing institutes.

(11) **FHB** should take reference from the experience of other cities and consider establishing a registration/certification system for Chinese medicine pharmacists, so as to enhance their professional status and recognition.

Publicity and Public Education

(12) **DH** should step up its publicity efforts to educate the public to differentiate between pCm and “CM health products”.

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